

117TH CONGRESS  
2D SESSION

# S. 4336

To require the Secretary of Health and Human Services, in consultation with the Director of the Cybersecurity and Infrastructure Security Agency, to annually review and as appropriate update guidance for industry and Food and Drug Administration staff on medical device cybersecurity, and for other purposes.

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## IN THE SENATE OF THE UNITED STATES

MAY 26, 2022

Ms. ROSEN (for herself and Mr. YOUNG) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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## A BILL

To require the Secretary of Health and Human Services, in consultation with the Director of the Cybersecurity and Infrastructure Security Agency, to annually review and as appropriate update guidance for industry and Food and Drug Administration staff on medical device cybersecurity, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Strengthening Cyber-  
5       security for Medical Devices Act”.

**1 SEC. 2. GUIDANCE FOR INDUSTRY AND FDA STAFF ON MED-****2           ICAL DEVICE CYBERSECURITY.**

3           (a) IN GENERAL.—Not later than 2 years after the  
4 date of enactment of this Act, and every 2 years there-  
5 after, the Secretary of Health and Human Services (re-  
6 ferred to in this Act as the “Secretary”), in consulta-  
7 tion with the Director of the Cybersecurity and Infrastructure  
8 Security Agency, shall review and, as appropriate and  
9 after soliciting and receiving feedback from medical device  
10 manufacturers, health care providers, and patient advo-  
11 cates, update the guidance entitled “Content of Premarket  
12 Submissions for Management of Cybersecurity in Medical  
13 Devices” (or a successor document).

14           (b) UPDATING SPECIFIC PROVISIONS.—In updating  
15 the guidance under subsection (a), the Secretary may up-  
16 date specific provisions of the guidance, after notice and  
17 comment, without reissuing the guidance.

**18 SEC. 3. RESOURCES REGARDING CYBERSECURITY OF MED-****19           ICAL DEVICES.**

20           Not later than 180 days after the date of enactment  
21 of this Act, and not less than annually thereafter, the Sec-  
22 retary shall update public information provided by the  
23 Food and Drug Administration, including through the  
24 webpage on medical devices on the website of the Food  
25 and Drug Administration, with information regarding im-  
26 proving cybersecurity of medical devices. Such information

1 shall include information on identifying and addressing  
2 cyber vulnerabilities for health care providers, health sys-  
3 tems, and medical device manufacturers, and how such en-  
4 tities may access support through the Cybersecurity and  
5 Infrastructure Security Agency and other Federal entities,  
6 including the Department of Health and Human Services,  
7 to improve cybersecurity of medical devices.

8 **SEC. 4. GAO REPORT.**

9 Not later than 1 year after the date of enactment  
10 of this Act, the Comptroller General of the United States  
11 shall publish a report identifying challenges in cybersecu-  
12 rity for medical devices, including legacy devices that may  
13 not support certain software security updates. Through  
14 such report, the Comptroller General shall examine—

15 (1) challenges for medical device manufactur-  
16 ers, health care providers, health systems, and pa-  
17 tients in accessing Federal support to address  
18 vulnerabilities across Federal agencies; and

19 (2) how Federal agencies can strengthen coordi-  
20 nation to better support cybersecurity for medical  
21 devices.

